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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard Wisniewski

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Examiner: Unknown

Title: CRYOPRESERVATION VIAL APPARATUS AND METHODS

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on March 07, 2002.

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Attorney for Applicants
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Date of Signature: March 07, 2002.

To: Commissioner for Patents
Washington, D.C. 20231

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PRELIMINARY AMENDMENT

Dear Sir:

Applicants respectfully request that the following amendments be entered, prior to examination of the above-referenced patent application.

In the Claims:

Please replace claims 1, 11-13 and 27 as follows:

1. A biopharmaceutical product cryopreservation system, for cryopreserving a biopharmaceutical product, comprising:
 - a cryopreservation compartment;
 - a cryopreservation fluid located within the cryopreservation compartment; and

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a biopharmaceutical product cryopreservation vial located within the cryopreservation compartment, and

the biopharmaceutical product cryopreservation vial comprising a body that comprises an oblong cross-section defining proximal and distal ends of the body, and at least one nucleating structure, coupled to at least one of the proximal and distal ends of the body, the at least one nucleating structure contacting the cryopreservation fluid, and the body comprising a cryogenically stable material that is compatible with biopharmaceutical products.

11. The biopharmaceutical product cryopreservation system of claim 10, wherein the cryopreservation fluid and the media absent the biopharmaceutical product are substantially identical in composition.

12. The biopharmaceutical product cryopreservation system of claim 10, wherein a thermal conductivity and/or a specific heat of the cryopreservation vial walls are substantially similar to those of the media or the cryopreservation fluid.

13. A method of cryopreserving biopharmaceutical products comprising providing a cryopreservation compartment;

locating a biopharmaceutical product cryopreservation vial within the cryopreservation compartment, wherein the biopharmaceutical product cryopreservation vial comprises a body that comprises an oblong cross-section defining proximal and distal ends of the body, and at least one nucleating structure, coupled to at least one of the proximal and distal ends of the body, and the body comprising a cryogenically stable material that is compatible with biopharmaceutical products;

locating a cryopreservation fluid in a space outside of the cryopreservation vial but within the cryopreservation compartment; and

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removing heat from the cryopreservation compartment, thereby freezing the cryopreservation fluid.

27. A biopharmaceutical product cryopreservation vial comprising:

a body that comprises an oblong cross-section defining proximal and distal ends of the body,

at least one nucleating structure, coupled to at least one of the proximal and distal ends of the body, and

the body comprising a cryogenically stable material that is compatible with biopharmaceutical products.

Please add the following new claims:

41. (New) The biopharmaceutical product cryopreservation system of claim 1, wherein the at least one nucleating structure comprises a first nucleating structure coupled to the proximal end of the body and a second nucleating structure coupled to the distal end of the body.

42. (New) The method of claim 13, wherein the cryopreservation fluid is located so as to contact the at least one nucleating structure.

43. (New) The method of claim 13, wherein the biopharmaceutical product cryopreservation vial is located within the cryopreservation compartment such that the freezing within the biopharmaceutical product cryopreservation vial moves in a direction away from the at least one nucleating structure and toward the body.

44. (New) The biopharmaceutical product cryopreservation vial of claim 27, wherein the at least one nucleating structure comprises a first nucleating structure coupled to

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the proximal end of the body and a second nucleating structure coupled to the distal end of the body.

45. (New) A biopharmaceutical product cryopreservation system, comprising:

a cryopreservation compartment adapted to hold cryopreservation fluid; and

a biopharmaceutical product cryopreservation vial adapted to be located within the cryopreservation compartment, and

the biopharmaceutical product cryopreservation vial comprising a body that comprises an oblong cross-section defining proximal and distal ends of the body, and at least one nucleating structure, coupled to at least one of the proximal and distal ends of the body, the at least one nucleating structure adapted to contact cryopreservation fluid when present within the cryopreservation compartment, and the body comprising a cryogenically stable material that is compatible with biopharmaceutical products.

46. (New) The biopharmaceutical product cryopreservation system of claim 45, wherein the cryopreservation compartment comprises one or more cooling surfaces.

47. (New) The biopharmaceutical product cryopreservation system of claim 46, wherein the one or more cooling surfaces comprise one or more internal surfaces of the cryopreservation compartment.

48. (New) The biopharmaceutical product cryopreservation system of claim 46, wherein the one or more cooling surfaces comprise two or more cooling surfaces spaced apart from one another.

49. (New) The biopharmaceutical product cryopreservation system of claim 48, wherein a distance between two or more cooling surfaces spaced apart from one another ranges from about 0.1 mm to about 1500 mm.

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50. (New) The biopharmaceutical product cryopreservation system of claim 45, wherein the biopharmaceutical product cryopreservation system comprises more than one cryopreservation vial.

REMARKS

Claims 1-40 were originally presented in the parent application. Claims 1, 11-13 and 27 have hereinabove been amended and claims 41-50 added to more particularly point out and distinctly claim the subject invention. Therefore, claims 1-50 remain in this case.

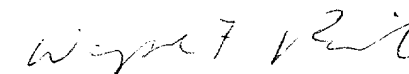
Support for the amendment to claims 1, 11-13, 27 and new claims 41-50 can be found throughout the specification and, therefore, no new matter has been added.

Applicants respectfully request substantive examination of claims 1-50.

Attached hereto is a marked up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version with Markings to Show Changes Made."

CONCLUSION

If a telephone conference would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided.



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Dated: March 07, 2002.

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Version with Markings to Show Changes Made

Please amend claims 1, 11-12, 13 and 27 as follows:

1. (Amended) A biopharmaceutical product cryopreservation system, for cryopreserving a biopharmaceutical product, comprising:
- a cryopreservation compartment;
 - a cryopreservation fluid located within the cryopreservation compartment; and
 - a biopharmaceutical product cryopreservation vial located within the cryopreservation compartment ~~and surrounded by the cryopreservation fluid~~, and
- the biopharmaceutical product cryopreservation vial comprising a body that comprises an oblong cross-section defining proximal and distal ends of the body, and at least one nucleating structure, coupled to a at least one of the proximal and distal end ends of the body, the at least one nucleating structure contacting the cryopreservation fluid, and the body comprising a cryogenically stable material that is compatible with biopharmaceutical products.
11. (Amended) The biopharmaceutical product cryopreservation system of claim 10, wherein the cryopreservation fluid and the media absent the biopharmaceutical product are substantially identical in composition.
12. (Amended) The biopharmaceutical product cryopreservation system of claim 10, wherein a thermal conductivity and/or a specific heat of the cryopreservation vial walls are substantially similar to those of the media or the cryopreservation fluid.
13. (Amended) A method of cryopreserving biopharmaceutical products comprising
- providing a cryopreservation compartment;

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locating a biopharmaceutical product cryopreservation vial within the cryopreservation compartment, wherein the biopharmaceutical product cryopreservation vial comprises a body that comprises an oblong cross-section defining proximal and distal ends of the body, and at least one nucleating structure, coupled to a at least one of the proximal and distal end ends of the body, and the body comprising a cryogenically stable material that is compatible with biopharmaceutical products;

locating a cryopreservation fluid in a space outside of the cryopreservation vial but within the cryopreservation compartment; and

removing heat from the cryopreservation compartment, thereby freezing the cryopreservation fluid.

27. (Amended) A biopharmaceutical product cryopreservation vial comprising:

a body that comprises an oblong cross-section defining proximal and distal ends of the body,

at least one nucleating structure, coupled to a at least one of the proximal and distal end ends of the body, and

the body comprising a cryogenically stable material that is compatible with biopharmaceutical products.

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